



Regulatory Dossier

Botanistat PF-64

21707 Nordhoff Street • Chatsworth, CA 91311

Tel: (818) 886-8067 • Fax: (818) 349-5649

www.botanigenics.com • email: info@botanigenics.com

Product Identification

Trade Name/Product #:	Botanistat PF-64
INCI Designation:	Phenoxyethanol (and) Caprylyl Glycol (and) Ethylhexylglycerin (and) Hexylene Glycol
Grade:	Cosmetic
Harmonized Tariff Code:	2909.49.1500
Country of Origin:	USA
Revision Date:	9/11/25

Composition & Material Identification

#	Constituent Name (INCI)	CAS#	EINECS#/ELINCS#	Min%	Max%	Constituent Function	Feedstock Origin
1.	Phenoxyethanol	122-99-6	204-589-7	45	65	Key Ingredient	Synthetic
2.	Caprylyl Glycol	1117-86-8	214-254-7	20	35	Key Ingredient	Synthetic
3.	Ethylhexylglycerin	70445-33-9	408-080-2	5	20	Key Ingredient	Synthetic
4.	Hexylene Glycol	107-41-5	203-489-0	5	20	Key Ingredient	Synthetic

Status

Halal and Kosher:

Please be advised, Botanistat PF-64 is not Halal or Kosher certified. To the best of our knowledge, Botanistat PF-64 is considered suitable for Hala and Kosher Certification. No animal ingredients/by-products or drinking alcohols are used in the production of Botanistat PF-64 and they are not expected in the finished product.

Vegan:

To the best of our knowledge, Botanistat PF-64 is considered suitable for Vegan use. No animal or animal by-products are used in the production of Botanistat PF-64. No animal testing has been conducted on Botanistat PF-64.

This information contained in this document is, to the best of our knowledge, true and accurate. No warranty, expressed or implied, is made or intended.



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Global Inventory Status:

Product Name	US	Canada	EU	Australia	China	Japan	Korea	Philippines
	TSCA	Inventory	EINECS/ ELINCS	AICS	IECSC	ENCS	ECL	PICCS
Botanistat PF-64	Exempt	DSL	Listed	Listed	Listed	Listed	Listed	Listed

Restrictions:

Country	Restriction (% and approved use if any)
USA	Not aware of any restriction
Canada	Not aware of any restriction
EU	2% maximum use level
Australia	2% maximum use level
China	2% maximum use level
Japan	2% maximum use level
Korea	2% maximum use level
Other:	Philippines: 2% maximum use level ASEAN: 2% maximum use level

Additives

Formaldehyde:

Formaldehyde is not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of formaldehyde is not expected.

Botanigenics does not analyze for presence of formaldehyde.

Preservatives:

Botanistat PF-64 is a preservative.

Parabens:

Parabens are not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of parabens is not expected. Botanigenics does not analyze for presence of parabens.



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Pesticides:

There are no pesticides used during the processing or manufacturing of Botanistat PF-64. Based on the source components and manufacture process, we do not expect pesticides to be present in Botanistat PF-64. Botanigenics does not regularly analyze for presence of pesticides.

PFAS:

PFAs are not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of PFAS is not expected. Botanigenics does not analyze for the presence of PFAs.

Phthalates:

Phthalates are not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of phthalates is not expected. Botanigenics does not analyze for presence of phthalates.

Impurities

Impurities/Residues/Catalysts/Monomers/By-Products:

Impurity	CAS#	% or ppm or ppb
Diethylene Glycol	111-46-6	< 1000 ppm
Ethylene Oxide		< 1 ppm
Phenol	108-95-2	< 5 ppm
1,4 Dioxane		< 1 ppm
Lead		< 1 ppm

D4/D5/D6:

D4/D5/D6 are not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of D4/D5/D6 is not expected. Botanigenics does not analyze for presence of D4/D5/D6.



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Diethylene Glycol-Ethylene Glycol:

Please refer to impurities table.

1,4-Dioxane:

1,4-Dioxane is not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of 1,4-Dioxane is not expected.

Botanigenics does not analyze for presence of 1,4-Dioxane.

Ethylene Oxide:

Ethylene oxide is not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of ethylene oxide is not expected.

Botanigenics does not analyze for presence of ethylene oxide.

Nitrosamines:

Nitrosamines are not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of nitrosamines is not expected.

Botanigenics does not analyze for presence of nitrosamines.

Residual Solvents:

Botanistat PF-64 is not expected to contain Class I, II, and III residual solvents according to USP <467> above the stated concentration limits. Botanigenics does not analyze for presence of residual solvents in Botanistat PF-64.

Sulfates:

Sulfates are not intentionally added during the manufacturing of Botanistat PF-64. Based on the source and manufacturing process, the presence of sulfates is not expected. Botanigenics does not analyze for presence of sulfates.



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Physical Attributes

Physical Chemical Properties:

Physical State:	Liquid
Color:	Clear, colorless to pale yellow
Odor:	Faint
Solubility in Water (20°C):	Dispersible
Flash Point:	121 ° C 250 ° F

ISO 16128:

The values of natural index (In), and natural origin index (Ino) according to ISO 16128 are as follows:

Product Name	In	Ino
Botanistat PF-64	0	0

Plant Derived: Yes ☐ No ☒

Component	
Plant Species	
Plant Part Used	
Genetically Modified (GMO)?	
*Nut/Seed Products: Yes ☐ No ☐	

**almonds, brazil nuts, cashews, chestnuts, cobnuts, hazelnuts (filberts), macadamia nuts, pecans, pistachio nuts, shea nuts, seed products, oils, derivatives, peanuts, sesame seed, sunflower seed, cotton seed, canola*

Animal Derived: Yes ☐ No ☒

BSE/TSE:

No animal fats, oil, milk products, or other animal products are used as components or in the manufacture of Botanistat PF-64. It is therefore considered to be free of BSE/TSE contamination.

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Allergens

Food Allergens:

Please be advised, while Botanigenics, Inc. does not analyze for allergens, based on the source, processing and manufacturing of the product we do not expect the presence of the following food allergens in Botanistat PF-64.

Gluten	Peanuts	Celery	Lupin
Shellfish	Soybeans	Mustard	Mollusks
Eggs	Milk	Sesame seeds	
Fish	Nuts	Sulphur dioxide	

Gluten:

While we do not test for the presence of gluten in Botanistat PF-64, the components used in Botanistat PF-64 are not derived from gluten associated grains. Therefore, we do not expect gluten to be present in the final material.

Fragrance Allergens:

Please be advised, we do not expect the presence of fragrance allergens above the limits stated in Regulation (EC) No 1223/2009, including its amendment Commission Regulation (EU) 2023/1545, in Botanistat PF-64. Botanigenics does not analyze for the fragrance allergens stated in Regulation (EC) No 1223/2009 in Botanistat PF-64.

Compliance

CMR:

Botanistat PF-64 does not contain any intentionally added composition components classified as carcinogenic, mutagenic or toxic for reproduction (CMR) as defined in Directive 1272/2008. None of these substances are expected to form during manufacture and are not expected to be present in Botanistat PF-64 except as unknown impurities at trace levels.

European Cosmetic Directive

The components of Botanistat PF-64 are compliant with the European Cosmetic Directive ((EC) No 1223/2009).



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IFRA:

Botanistat PF-64 is not included in the IFRA guidelines.

Nanomaterials:

To the best of our knowledge, Botanistat PF-64 is not considered a nanomaterial nor does it contain nanomaterials as defined by European Commission's definition of a nanomaterial ("A natural, incidental, or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number distribution, one of more external dimensions is in the size range 1 nm – 100 nm").

Prop 65:

Botanistat PF-64 does not contain any intentionally added composition components known to cause cancer or reproductive toxicity as defined in California Proposition 65. None of these substances are expected to form during manufacture and are not expected to be present in Botanistat PF-64 except as unknown impurities at trace levels. It is the responsibility of the end user to determine if its finished products require labeling under California Proposition 65.

SVHC:

Botanistat PF-64 does not contain any intentionally added composition components identified on the Substance of Very High Concern list under REACH. None of these substances are expected to form during manufacture and are not expected to be present in Botanistat PF-64 except as unknown impurities at trace levels.

Synthetic Polymer Microparticle:

"Synthetic polymer microparticle" is defined in the September 2023 Commission Regulation (EU) 2023/2055 amendment of Annex XVII to Regulation (EC) No 1907/2006. When evaluated against the definition cited within the regulation, Botanistat PF-64 does not contain synthetic polymer microparticles. We do not expect the product to fall within the scope of the proposed restriction. Botanigenics does not analyze for the presence of synthetic polymer microparticles in Botanistat PF-64.

It remains the responsibility of the end user to comply with the final microparticle regulation for the finished products they are placing on the market.

Volatile Organic Content:

None of the components in Botanistat PF-64 are classified as a VOC.



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Testing

Animal Testing:

Botanigenics, Inc. does not test any of its products on animals.

Human Safety/Testing Summary:

Test	Protocol	Date	Result
Dermal Irritation	RIPT	06/2005	Did not indicate a potential for dermal irritation
Dermal Sensitization	HRIPT	06/2005	Did not indicate a potential for allergic contact sensitization
Mucous Membrane Irritation (Eye)	HET-CAM	09/2005	Indicated virtually no ocular irritation potential

Environment/Sustainability

CITES and IUCN Red List:

To the best of our knowledge, Botanistat PF-64 does not contain any substance or material contained on any of the CITES Appendices, or on the IUCN Red List of endangered species (fauna and flora). None of these substances or materials are intentionally added or expected to form during manufacture, and based upon information from our raw material suppliers, are not expected to be present in the finished raw material.

RSPO:

Botanistat PF-64 does not contain any palm, or palm derived ingredients.